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MEDICAL DEVICES INDUSTRY OPPORTUNITIES IN JAPAN & CHINA



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MAINE INTERNATIONAL TRADE CENTER

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I. Summary of Opportunities

Japan ranks as the third biggest medical device market after the United States and the European Union, on track to expand even more with the percentage of seniors (65+ years) going from 24% in 2012 to 40% in 2050. Manufacturers that would like to sell their medical devices in Japan will have through the Japanese Pharmaceutical Affairs Law, which also applies to pharmaceuticals and cosmetics. Under the PAL law, a marketing approval, a license for Marketing Authorization Holder and a manufacturer license are given by the Minister of Health, Labor and Welfare (MHLW).¹

II. Industry Prospects

Japan's market for medical devices and materials continues to be among the world's largest. According to the latest official figures from the Ministry of Health, Labor and Welfare (MHLW) Annual Pharmaceutical Production Statistics, the Japanese market for medical devices and materials in 2012 was approximately \$32.5 billion (up 8.7 percent from 2011 in yen terms). Japan's total imports of U.S. medical devices were approximately \$7.4 billion in 2012. Based on preliminary reports from MHLW, the Japanese market for medical devices and materials was projected to have increased in yen terms in 2013. In the near term, the market is expected to increase in a measured fashion due to Japan's aging population and continued demands for advanced medical technologies. The market remains heavily dependent on imports, especially sophisticated medical technologies. U.S. exports to Japan were limited to a 23 percent market share according to the official figures. However according to the American Medical Devices and Diagnostics Manufacturers' Association (AMDD), a trade association of Japanese operations of U.S. medical devices and diagnostics companies, 58% of "new medical devices" approved in Japan during the last 7-year period were from its member companies.

The market remains heavily dependent on imports, especially sophisticated medical technologies. U.S. exports to Japan were limited to a 23 percent market share according to the official figures. However, when including local and third country productions, U.S. firms have achieved a much higher market share than the official statistics. U.S. medical device companies produce a wide variety of medical devices, but they are especially strong in sophisticated segments of the market such as pacemakers, advanced interventional cardiology products, orthopedic implants, laser surgical equipment, and advanced diagnostic imaging equipment. In the near term, the market is expected to increase in a measured fashion. Japan's aging population, continued demand for advanced medical technologies and the government of Japan's measures to promote healthcare industry will sustain growth. Espicom Business Intelligence estimated that Japan's medical device market will exhibit a compound annual growth rate (CAGR) of 2.5 percent from 2013 to 2018.²



Prime Minister Shinzo Abe's economic revitalization and growth strategy introduced in June 2013 includes the promotion of domestic pharmaceutical and medical device industries. Japan thus identified the medical device and pharmaceutical industries as key areas for business promotion and development. The strategy includes measures such as accelerating regulatory approvals and eliminating so-called "medical device lags" and "drug lags" in market introduction as well as rewarding innovative medical devices and pharmaceuticals among other measures. As a part of the strategy, the Government obtained Diet approval in November 2013 of amendments to the Pharmaceutical Affairs Law (PAL). The Diet revised the law to reflect the characteristics of medical devices separately from pharmaceuticals, and the medical review process is expected to be further improved through the revised PAL and related regulations.

While the regulatory environment is expected to continue improving and the market for U.S. medical equipment in Japan remains strong, U.S. firms face challenges with pricing and reimbursement due to the GOJ's efforts to contain overall healthcare costs as a result of Japan's aging population. The GOJ implemented pricing policies, such as Foreign Average Price (FAP), to cut medical device reimbursement rates. In 2014 reimbursement revisions, the GOJ again changed the FAP rule by excluding the highest price under certain conditions in the foreign average price calculation method. GOJ also changed the recalculation rule by reducing the foreign average price multiplier of 1.5 times to 1.3 times under certain conditions. Despite the fact that the FAP rule has substantially narrowed foreign price differentials between Japan and overseas markets through the past seven reimbursement revisions, the price differential still remains as an issue to be solved within the GOJ. Also, as national health expenditures are expected to increase further in coming years, the GOJ will continue to take measures to contain overall healthcare costs including reducing medical device reimbursement rates.

Sub-Sector Best Prospects

Given Japan's aging population and the increasing number of patients with chronic and life-style diseases, medical devices that alleviate pain, complement lost functions, and improve the quality of life should show steady growth in demand. Also, the market for inhome care devices, technologies, and health IT related products is expected to grow as the number of people in out-patient care increases. Due to stronger consumer health concerns, other promising growth areas include self-care and preventive care medical devices and products.³

Opportunities

Japan has a fast-aging demographic profile, with relatively prosperous seniors holding increasing expectations for improved quality of life in their late years. The Japanese health care system places increasing emphasis on improved treatment and health maintenance. This will generate further opportunity for the types of innovative solutions at which U.S. industry excels. Sophisticated, new



medical devices, regenerative medicine and Health IT are sub-sectors that are particularly suited to meeting Japan's healthcare needs. The Japanese market for medical devices is large and established reaching USD 32.5 billion in 2012. The official figures for U.S. exports to Japan were limited to a 23 percent market share; however, according to the AMDD, an industry organization that represents the Japanese operations of 67 U.S.-based companies, approximately 60 percent of "new medical devices" approved in Japan were from AMDD member companies. Espicom Business Intelligence estimated that Japan's medical device market will exhibit a compound annual growth rate (CAGR) of 2.5 percent from 2013 to 2018, and also the firm estimated that all individual product categories should experience positive growth with the top performers being orthopaedics and prosthetics (4.7 percent CAGR in local currency terms) and patient aids (4.0 percent CAGR).

On top of this quantitative base and qualitative demand, Prime Minister Abe's growth strategy calls for promotion of the pharmaceutical, medical device and biotechnology industries. The strategy includes measures such as accelerating regulatory approvals and eliminating so-called "medical device lags" and "drug lags" in market introduction as well as rewarding innovative medical devices and pharmaceuticals among other measures. Although the GOJ's policy programs are basically targeted to enhance the international competitiveness of Japanese industries, these programs should also benefit U.S. medical companies that can offer innovative products to Japanese patients. As a part of the strategy, the government obtained Diet approval in November 2013 of amendments to the Pharmaceutical Affairs Law (PAL). The Diet revised the law to reflect the characteristics of medical devices separately from pharmaceuticals, and the medical review process is expected to be further improved through the revised PAL and related regulations.

Main Competitors

The major product categories comprising Japan's domestic medical device production include: diagnostic imaging equipment; therapeutic and surgical equipment; biophenomena measuring and monitoring systems, home therapeutic equipment, dialyzers, and endoscopes. Japanese medical device companies maintain high market share in those product segments. Top Japanese medical device companies, in terms of sales, include Terumo, NIPRO, Olympus Medical Systems, Toshiba Medical Systems, Hitachi Medico, Nihon Kodan, and Fukuda Denshi. U.S. medical device companies produce a wide variety of medical devices, but they are especially strong in sophisticated segments of the medical market such as pacemakers, advanced interventional cardiology products, orthopedic implants, laser surgical equipment, and advanced diagnostic imaging equipment. Most major U.S. and foreign medical device firms have either a Japan office or a Japanese partner. As such, new-to-market U.S. companies will face strong competition not only from Japanese companies but also from U.S. and multinational firms already in the market. In April 2009, Japan based U.S. medical device manufacturers launched a



new association called the American Medical Devices and Diagnostics Manufacturers Association (AMDD, amdd.jp/en). The AMDD currently has more than 65 member companies.⁴

Pharmaceuticals

The Japanese pharmaceutical market is the world's second-largest, with 2013 sales estimated at \$115 billion. Japan accounts for a little less than 10 percent of the global pharma market.⁵

The country's rapidly ageing population and its medical needs have sustained the industry, composed of a clutch of major pharma companies and hundreds of smaller firms, but a general dearth of pharmaceutical innovation and little international expansion has created little growth.

In recent years, however, a number of developments have arisen to challenge Japan's pharma status quo, with indications that its market is becoming more open, both to foreign companies entering the Japanese market and to Japanese companies investing abroad.

As well as showing rising signs of Japanese companies seeking opportunities outside Japan's shores, foreign companies have been finding significantly more success in penetrating the Japanese market in recent years. Traditionally international firms have struggled to adapt to Japan's regulatory system and working culture, but today most major pharma companies maintain a successful presence, despite occasional incidents like Novartis's recent threat of suspension by the Japanese Ministry of Health, Labour and Welfare over allegations of data manipulation.

Government reforms like greater harmonisation with EU and US regulatory regimes and R&D tax credits have helped persuade companies to set up shop in Japan. The country has gradually become a popular destination for multi-regional clinical trials (MRCTs) since 2006, when bridging studies - studies to determine whether foreign trial results are applicable to patients in Japan - were allowed to be included in MRCTs, shortening the time and expense involved in getting new drugs to Japanese patients safely.

Japan is also attempting to incentivise a much higher use of generic drugs - which have struggled to find a place in the market until recently - as a means to reduce healthcare spending. Unconfirmed reports suggest the government wants generic penetration of 60% in 2017, up from just 30% in 2014. "If the target is true, domestic suppliers will face serious difficulties meeting it," reads a Thomson Reuters report on the Japanese generics market. "Unsurprisingly then, Japan is seen as a largely untapped market by foreign generic manufacturers, one that until recently was all but closed to them."

Indeed, generic manufacturers from around the world - but especially generic specialists such as India - are looking to Japan as a source of future expansion. According to the Economic Times, Indian generics giants including Dr Reddy's, Lupin, Sun Pharma and Glenmark are exploring options for tapping into the growing Japanese generics market.⁶

III. Japan Market Overview

As the world's fourth-largest buyer of American products and the world's third-largest economy, Japan, among the most dynamic and advanced countries in the world, is a market that should be considered by all American exporters. Japan is a technology powerhouse, a proving ground for consumer goods and services, and in the social and commercial vanguard of developed market demographics. Further, Japanese companies are also major investors in the United States, and as a result Japan sees dozens of visits by senior U.S. state and city officials annually. While the reasons U.S. firms engage with Japan are diverse, the strategic and tactical importance of the Japanese market is critical not only for their business in Japan, but in the United States and third-country markets as well.

Japan continues to enjoy attention in the business news this year owing to a variety of factors, including the strong performance of the Japanese stock market in 2013, continued brighter business and consumer sentiment, a yen that has seemingly stabilized at a level sharply lower than that of recent years, and the apparent end of stubborn deflation. The new economic policies linked to these developments are known collectively as "Abenomics"-- a three pronged strategy of bold monetary loosening, fiscal stimulus centered on infrastructure spending, and growth-oriented structural reform. While the implications and ultimate success of this strategy in reigniting long-term growth in Japan are uncertain, it has drawn considerable attention from U.S. businesses.

The U.S., Japan and ten other countries are negotiating the Trans-Pacific Partnership (TPP). With Japan's participation, its members would account for nearly 40 percent of World GDP. Moreover, the liberalization expected to be required of TPP member countries may play an important role in promoting the domestic economic reforms likely to be called for under "Abenomics." As of May 2014, the U.S.-Japan TPP talks have been proceeding vigorously, with most topics already or nearly agreed upon.

While Japan has made significant steps toward economic healing following the tragic combined earthquake, tsunami, and nuclear incident of March 2011, lasting changes on various levels remain noticeable, including idled nuclear power plants. In particular, greater levels of manufacturing by

Country Profile

- **Full name:** Japan
- **Population:** 127,103,388 (July 2014 est.)
- **Median Age:** 46.1 years
- **Largest District:** Tokyo
- **Area:** 377,915 sq km
- **GDP:** USD \$4.77 trillion (2014 est.)
- **GDP per capita:** USD \$37,800 (2014)
- **Unemployment rate:** 3.6% (2014)
- **Monetary unit:** Yen (JPY)
- **Main exports:** motor vehicles; semiconductors; iron and steel products; auto parts; plastic materials; power generating machinery
- **Investment in fixed capital:** 22.2% of GDP (2014)
- **Inflation rate:** 2.8% (2014)

Source: CIA World Factbook



Japanese companies outside of Japan, increased fuel imports and a weakening yen have turned Japan's multi-decade trade surplus into a trade deficit.

Japan remains the world's third-largest economy, after the United States and China, with a GDP of almost \$6 trillion. Japan is the fourth-largest export market for U.S. goods and services, and our fourth-largest trading partner overall. In 2013 the U.S. exported \$65 billion in goods to Japan. The United States runs a persistent trade deficit with Japan in merchandise, and a surplus in services.

Japan is the second-largest foreign investor in the United States, with a cumulative investment of approximately \$310 billion.

During 2013 the Japanese yen weakened appreciably and is currently near 5- year lows against the dollar. Even so, U.S. products remain competitive in Japan.

Japan's large government debt, which totals over 200 percent of GDP, and an aging and shrinking population are major challenges confronting the economy, but the latter can also present opportunities for U.S. companies.

In 2013 the top exporters to Japan were China, the United States, Australia, Saudi Arabia, South Korea, the UAE, and Indonesia. The top importers from Japan were China, the United States, South Korea, Taiwan, and Hong Kong.

The United States-Japan alliance is a cornerstone of U.S. security interests in Asia and is fundamental to regional stability and prosperity. The U.S.-Japan alliance continues to be based on shared vital interests and values. These include stability in the Asia-Pacific region, the preservation and promotion of political and economic freedoms, support for human rights and democratic institutions, and securing of prosperity for the people of both countries and the international community as a whole. Japan is one of the world's most prosperous and stable democracies.

Market Challenges

The degree of difficulty in penetrating the Japanese market depends on the product or service involved. Key variables include the degree of local or third-country competition, the number of regulatory hurdles to be overcome, and cultural factors such as language (both spoken and written), service and quality expectations, and business practices. Tariffs on most imported goods into Japan are low. However, cultural, regulatory, or other non-tariff barriers exist that can make market entry difficult. These can include Japanese import license requirements, restricted or prohibited imports, temporary entry of goods, certifications, standards, labeling requirements, etc.



Market Opportunities

U.S. companies wishing to enter the Japanese market should consider hiring a reputable, well-connected agent or distributor, and cultivating business contacts through frequent personal visits. Japan's business culture attaches a high degree of importance to personal relationships, and these take time to establish and nurture. Patience and repeated follow-up are typically required to clinch a deal. The nature and pace of dealmaking in Japan are quite different from those in the United States. U.S. business executives are advised to retain a professional interpreter, as many Japanese executives and decision-makers do not speak English or prefer to speak Japanese.⁷



IV. Summary of Opportunities

China has been one of the fastest growing economies in the world with a GDP of 7.7 percent in 2013. China's medical device market is ranked second largest in the world. Driven by both an increase in discretionary income and a population that is aging faster than any other nation's population, the market has been growing at about 20 percent since 2009. It is expected to maintain this pace over the next three to five years, far exceeding the predicted growth rate of the global market. By 2020, China will have 400 million people who are 60 years-old or older, and 100 million older than 80. By 2050, a third of the 1.4 billion Chinese will be at least 60.⁸

V. Industry Prospects

China has become the world's second largest medical device market. Based on a recent report by the China Association of Medical Device Industry (CAMDI), China's medical equipment market has been growing at an average of 20 percent annually since 2009 and is expected to maintain the same growth rate through 2015.

According to the information from China Pharmaceutical Materials Association Medical Device Branch, the market size is expected to reach RMB300 (over \$48) billion by 2015. The driving factors include fast economic growth, the world's largest population, a burgeoning, aging population as well as government efforts to create better healthcare services. The government has invested heavily in the healthcare infrastructure and the provision of basic health insurance for all of its citizens.

Currently China's medical device market has two distinct categories: 1) domestic manufacturers who supply low to mid-range products 2) foreign-sourced, high-end products supplied by large companies like GE, Philips, and Siemens. According to Shanghai FDA, by the end of 2013 there were a total of 17,800 domestic medical device manufacturers and 180,000 distributing companies. China's total sales volume was RMB 215 (\$34.68) billion in 2013, representing a growth of 22% since the close of fiscal year 2012.

The United States ranks #1 in the import medical device market, followed by Germany and Japan. These three countries represent the majority share of China's imports.

According to statistics from the China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCMHPIE), China's import and export value of medical equipment reached \$34.31 billion in 2013, an increase of 14% over 2012.



China has over 16,000 hospitals, 85% of which are publicly-owned. The Chinese hospitals consider U.S. products to be of superior quality as well as the most technologically advanced and they particularly welcome medical equipment and products with high-technology content. At the same time, domestic medical device companies are consolidating, upgrading quality, and beginning to compete in medium-level technology niches. With the government policy to align to supporting and encouraging medical device innovations, some domestic manufacturers such as Shenzhen Mindray are growing stronger and are already competing with foreign suppliers.

Given the status of the Chinese medical device market, significant potential exists for U.S. companies interested in entry or expansion in the Chinese market. On the other hand, the new healthcare reform, which started in 2009, is at the stage of advancing the reform on public hospitals. An accumulated investment of over RMB 2,242 billion (\$359 billion) has been invested by the government during the last five years to improve the healthcare infrastructure. The reform will definitely impact future medical device sales opportunities in China.

Companies interested in entering the Chinese market should realize they must overcome existing barriers in an uncertain and changing regulatory environment. Recently, China's State Council announced changes in the Regulation for Supervision and Administration of Medical Devices (Order 650), slated for implementation on June 1, 2014. Order 650 is the revision of the old regulation Order 276 which was implemented in 2000. As the regulator of medical devices, China Food and Drug Administration (CFDA) is expected to issue a number of technical documents on June 1st for implementing this new regulation. Compared with the old regulation, noticeable changes include extending validity of the registration certificate to five years; adopting a notification system to replace the registration system for all Class I products; requiring Chinese language on the product manual, labels, and packaging labels; requiring clinical trials inside China for the Class II and Class III medical devices that are not on the CFDA's exemption catalog. Additional issues and challenges that the U.S. exporters will face include pricing, tender, and bar code systems that are delaying entry into the Chinese medical device market.

Sub-Sector Best Prospects

The best-selling prospects in the medical device sector include:

- In vitro diagnostic equipment and reagents: Clinical and diagnostic analysis equipment, diagnostic reagents, medical test and basic equipment instruments, and point of care testing (POCT).
- Implantable and intervention materials and artificial organs: Interventional materials, implantable artificial organs, contact artificial organs, stent, implantable materials, and artificial organ assisting equipment.
- Therapeutic products: Tri-dimensional Ultrasonic-focused therapeutic systems, body rotary Gamma knife, simulator, linear accelerator, laser diagnostic and surgical equipment, nuclide treatment equipment, physical and rehabilitation equipment.



- Medical diagnostic and imaging equipment: Black & white and colored supersonic diagnostic units, sleeping monitor, digital X-ray system, MRI, CT, DR, and ultrasound equipment.
- Surgical and emergency appliances: Anesthesia ventilation systems and components: high frequency surgical equipment, high frequency and voltage generators.
- Healthcare Information Technology related equipment and products: Medical software, computer-aided diagnostic equipment, and hospital information systems (HIS, CIS, and HLT).
- Medical equipment parts and accessories.⁹

Opportunities

Medical Device Market

China offers significant potential for U.S. companies interested in entering and expanding into the Chinese medical device market. In 2013, the medical equipment market reached a size of RMB215 (USD 34.68) billion for the first time in history, representing a growth of 22 percent since the close of 2012. The market size is expected to exceed RMB300 (USD 48.39) billion by 2015. With a rising Chinese middle class and improved health insurance to cover all nationals, the demand for quality equipment and supplies is growing at an unprecedented pace.

China's medical device market is dominated by domestic suppliers, the majority of which generally lack the expertise and experience deemed appropriate by Western standards. While only a few Chinese medical device companies are upgrading to provide some mid- to high-range technology and products, the high-tech large medical equipment is dominated by foreign suppliers. Compared with domestic products, imported products are better accepted by the Chinese hospitals and the Chinese view foreign medical device companies as more credible than their Chinese counterparts. Therefore, the Chinese healthcare market is poised to be explored by those foreign enterprises that have interest.

China is the most promising medical device market in the world. The average annual growth rate has been over 20 percent since 2009 and is expected to maintain that growth rate during the next three to five years. Based on a recent report by Medical Device Branch, China Pharmaceutical Materials Association, the medical equipment market reached a total size of RMB215 (USD 34.68) billion in 2013 for the first time in history, a yearly growth rate of 22 percent. The market size is expected to exceed RMB300 (USD 48.39) billion by 2015. Driving factors include world's largest population and aging population, the government's increased investment in establishing and improving the healthcare infrastructure, and improvement of basic health insurance for all the population. This has created huge demand for better healthcare services and thus needing for medical devices and products in China.



Currently, China's medical device market has two distinct categories: 1) domestic manufacturers who supply low to mid-range products; 2) foreign-sourced, high-end products supplied by large companies like GE, Philips, Siemens, etc.

According to statistics from the China Chamber of Commerce for Import and Export of Medicines and Health Products (CCCMHPIE), China's total import and export value of medical equipment reached 34.31 billion U.S. dollars in 2013, an increase of 14.13 percent over 2012. The top three medical device exporters to China by country are the United States, Germany, and Japan.¹⁰

Two factors are at work driving health care spending in China. With rising per capita incomes, China's increasingly affluent consumers are demanding the latest in medical treatment and services. At the same time, changing diets and air and water pollution are causing a rise in the incidence of cancer, heart, diabetes and other chronic diseases among China's population. Both are creating new opportunities for pharmaceutical, medical device, hospital management and companies that provide a wide range of health-care products and services.

According to a report by the World Health Organization (WHO), China accounted for over three million newly diagnosed cases of cancer, almost 22 percent of the global total, and 2.2 million cancer deaths, 27 percent of the world's total, in 2012. In addition to being hard hit by cancer, the WHO also estimates that approximately 230 million Chinese currently suffer from cardiovascular disease, and that annual cardiovascular events will increase by 50 percent between 2010 and 2030 based on population aging and growth alone. The incidence of diabetes tells a similar story. Almost one-in-three global diabetes sufferers today is in China, with approximately 114 million adults afflicted by the disease.

In order to combat these growing health issues, many of China's 22,000 hospitals will need to be substantially upgraded or replaced in the coming years. In addition, the Chinese government is counting on foreign-owned hospitals, the ownership of which was previously highly restricted or forbidden, to fill some of the void. The government's goal is to increase private hospital service contribution to 20 percent of the total hospital service value by 2015, from less than 10 percent currently.

In August of this year, China announced a pilot project whereby overseas investors can establish wholly foreign-funded hospitals, either by acquisition or greenfield, in seven of its cities and provinces. As a result, private equity and other substantial investors are actively searching for new investment opportunities in hospitals — and companies with the latest in health care technology.¹¹

Trends

Demand for Imports. During BMI Espicom's most recent study period, imports of medical equipment have grown 20.8% through 2012.6 Diagnostic imaging is expected to account for 40.4% of the medical device market in 2013, according to the firm's latest data (Figure 2). Consumables represent 16.6% of



the market, followed by patient aids (14.1%) and orthopedics (5.9%). Seventy percent of high-end medical devices are imported, according to Hua Yutao, director of China Biology

Technology Development Center. Only about 2000 companies in China produce Class III devices, Yutao said at a CEO summit in Shanghai.

Expanding Middle Class. Increasing affluence has led to Western-style lifestyles and associated diseases. The cardiac surgery device market, for example, is forecast to grow at a CAGR of 13% through 2018. “The increasing integration of high-fat diets into Asian cultures is leading to an increase in coronary artery bypass graft procedures,” according to Kamran Zamanian, president and CEO of iData Research.

Targeted Growth. Medical imaging, patient monitoring, in vitro diagnostic (IVD) technology, and high value consumables are the sectors with the greatest growth potential in the coming years. There are 7100 hospitals at the county level in China, only 800 of which have MRI equipment, according to Time Medical Systems CEO Ma Qiyua, adding that imaging companies face a historic opportunity as China upgrades its medical infrastructure.

China’s IVD Market. Currently valued at more than \$4.5 billion, it doubles every three years, according to Whitney Research analyst Nat Whitney. “It will surpass the United States to become the world’s largest IVD market within the next 10 to 15 years,” he predicts.¹²

Medical equipment, such as x-ray, ultrasound and other imaging equipment will account for at least one-third of China’s medtech market value. With that said, other product sectors are growing more rapidly. Products such as consumables, implantable and dental products, endoscopy and in-vitro diagnostics (IVD)*—while each accounting for no more than one-fifth of the market’s current value—are projected to grow at least 20% per annum over the next three years.

Growth will likely be led by sub-segments - such as dental products, endoscopy, consumables and IVD - that have higher growth rates than the overall market. These higher growth segments illustrate a gradually maturing Chinese healthcare market and should encourage manufacturers to shift their product portfolios to serve the future China medtech ecosystem.¹³

U.S. and China

- The United States has the world’s largest medical device industry, and 20 of the world’s 30 largest medical device manufacturers are based here. These firms have been able to expand their share of the growing Chinese market through exports; during 2008–12, exports to China of orthopedic, cardiovascular, and imaging devices collectively rose by 150% to \$1.7 billion (figure 2). During this time, the United States emerged as the top exporter of medical devices to China and presently supplies nearly one-third of the country’s total import market for these goods.



- Nearly one-quarter of the U.S. industry's export growth to China during 2008–12 was driven by China's high demand for three types of devices in particular: stents, ultrasound devices, and MRI devices. Together, imports from the U.S. of these three goods grew by 236% to \$551 million over this four-year period.¹⁴

Entering the market

With regard to health industries specifically, non-traditional players are also expressing rising interest, e.g. Alibaba is exploring healthcare institutions/landscape transformation and specifically looking into establishing an O2O platform for an e-pharmacy. Such investment, in conjunction with other key market growth factors, will lead to the augmented use of health products, including drugs and medical technology (medtech) products. There are four top priorities for companies operating in the China medtech space: (1) dissecting the market's growth; (2) understanding the government's role; (3) keeping up with Chinese healthcare reform; (4) staying competitive. Grasping these four concepts will be the first step for MNC executives looking to achieve sustainable growth in this country.

Similar to other industry spaces, the medtech market in China offers great opportunities for MNCs. PwC's best estimates, combining data from third parties and our own research, are that the China medical device market is anticipated to reach approximately US\$50 billion by 2017, reflecting roughly a 20% compound annual growth rate (CAGR) from 2013.

The key underlying growth drivers are the aging population, greater affordability of care, changing lifestyles and expanding healthcare coverage. In light of these numbers, it would be folly for medtech MNCs not to expand their China strategy.

Key sub-segments of the current China medtech market are diagnostic imaging (38%), consumables (16%) and patient aids (15%). However, while the opportunity in China may be great, painting the world's most populous nation with one broad brushstroke would be a gross error. Medtech companies must fully understand China's market characteristics, and cultural nuances, to ensure sustainable market adoption and acceptance of their products. In particular, successfully navigating the China medtech ecosystem requires executives to have a strong grasp of the country's market opportunities, the government's role in the industry, evolving healthcare reform efforts, and local competition.¹⁵

Pharmaceuticals

In 2012, output from the pharmaceutical industry grew 21.7% to RMB1.82 trillion; revenue from the industry grew 20.1% to RMB1.8 trillion; profits from the industry grew 20.4% to RMB183.3 billion; the industry exported \$47.6 billion worth of drugs and imported \$33.4 billion worth of drugs, up 6.9% and 15.9% respectively from 2011; investment in the pharmaceutical industry grew 34.6% to RMB356.5 billion.



In 2011, the State Food and Drug Administration approved the registration of 718 drugs, including 644 domestic drugs and 74 imported drugs. Of the 644 domestic drugs, 569 were chemical drugs, 50 were traditional Chinese medicine and 25 were biomedicine. Of the 74 imported drugs, 68 were chemical drugs, 2 were traditional Chinese medicine and 4 were biomedicine.

Pharmaceutical Companies

As of the end of 2009, China had 6,807 pharmaceutical companies; the top 3 pharmaceutical companies captured a 20% market share (compared to 90% in the US and 73% in Japan) wholly foreign owned or Chinese-foreign pharmaceutical companies accounted for 30% of total number and 27% of total revenue. By the end of 2015, China hopes to have five pharmaceutical companies that post RMB 50 billion (USD 8.06 billion) or more in annual revenues and 100 pharmaceutical companies that post RMB 10 billion (USD 1.61 billion) or more in annual revenues, and the top 100 pharmaceutical companies are expected to be responsible for 50% of industry revenue.

Drugstore Chains in China

China's rapid aging population has fueled the growth of drugstore chains. The 100 biggest drugstore operators posted a combined RMB 59.6 billion (9.6 billion) in revenues in 2011, accounting for 39.7% of total drug retail sales. As of the end of 2011, China had 3,012 drugstores.¹⁶

Between 2007 and 2012, Chinese investment in biomedical R&D grew at a compound annual rate of 33 per cent, compared with an average 7 per cent in the rest of Asia-Pacific, according to McKinsey, the consultant. This increased spending is beginning to produce results: the number of Chinese papers in respected life science journals has risen more than sixfold between 2001 and 2013, says Fangning Zhang of McKinsey in Shanghai.

Skills shortages are another obstacle being gradually overcome, as China's universities churn out young scientists and those trained in the west return home.¹⁷

To drive business, MNCs need to consider the following:

1. The implications of macrotrends

With the government's push towards expanding healthcare coverage for the country, several effects are coming into place:

- a. Hospital groups are forming, and significant activities around public hospital restructuring/privatization are being seen. With private investment pouring into hospitals



and the public's higher expectations of these institutions, the question becomes how MNCs can take advantage of this shift, e.g. matching premium private hospitals' value proposition with MNC product offerings. What does more money mean for physicians at these hospitals? What are the implications for pharmaceutical MNCs' strategy? Moreover, in the short-term, for instance, these hospitals may serve as a gateway to patients who have more money to spend on both insurance coverage and higher-end treatments.

- b. Another key trend is the transformation of reimbursement, with the Chinese government piloting various schemes to control healthcare spending. Take for example, the pay-per-disease approach, whereby medical insurance does not cover any payments beyond a pre-defined level per disease. A related initiative is reimbursement pre-payment. Medical insurance bureaus pre-pays the allocated total reimbursement budget to the hospitals, and this allocation amount is calculated based on schemes, such as using per capita medical expenses as calculation basis. Any expenses beyond pre-payment budgets are absorbed by hospitals, while any savings may be kept as incentives.
- c. Physicians are being rated against a number of factors for salary and promotion consideration, ranging from the number of patients they treat to the quality of care and service, as well as the academic research and publications they produce. In other words, medical practitioners have a diversifying set of key performance indicators to meet in order to advance.

2. The evolution of physicians' needs

We have observed in China a shift in physicians' clinical needs from product-centric to solution-centric, similar to the mature markets. The latter concentrates on how to provide therapies to diseases (versus merely on how to treat their symptoms). More specifically, physicians practicing in big city, big hospitals are requesting information beyond product efficacy, and are looking to acquire knowledge on providing better therapy solutions to patients.

Physician's new needs cannot be fulfilled by a sales force alone. Pharmaceutical companies must consider all facets from the physician to multichannel approaches, marketing and medical affairs. How are corporations supporting physicians? Can they help to offer broader research support or improvements in operation efficiencies, etc.?

3. Decreasing face time with physicians

As face-to-face (F2F) interactions between the big city, big hospital physician and patient is clearly in decline, it becomes worthwhile to consider mixed channels for communication. Technology-enabled trends from the Western world can be translated here. Invest in how digital solutions, e.g. the use of web, mobile, social networks, wireless devices, and physician portals, can play a role in liaising with technology-savvy physicians, and potentially with other key stakeholders. At the same time, tailor the traditional sales forces F2F approach for physicians in the broader market. In the long run, implementing approaches will set physicians and



institutions ahead – such solutions will manage a patient’s disease, and not just address symptoms.¹⁸

Yet this is set to change. Government spending on R&D is expected to reach 2.5 per cent by 2020 as it strives to get into line with developed markets. This should benefit the pharma industry – but the big multinationals with Chinese operations are still expected to lead the way in terms in investment.¹⁹

Change in Customer Dynamics

It is critical for pharmaceutical companies to understand how health care reform in China is changing the way that three key customer groups (city hospitals, county hospitals, and the basic health-care system) operate—and therefore changing the composition of the market.

City hospitals will account for about 50 percent of growth from 2011 through 2020. These hospitals provide better economics, relative to county hospitals and community and township health-care centers, for pharmaceutical companies thanks to their strong demand for pharmaceuticals and the reasonable costs that pharmaceutical companies incur in selling to these organizations. As a result, city hospitals will continue to be a hotly contested market among MNCs and local companies.

County hospitals, however, will become an increasingly important market. The government is increasing its investment in new infrastructure and physician training to improve county hospitals’ capabilities and is adopting reimbursement policies that encourage people to go to the county facilities instead of the big-city hospitals. That’s why county hospitals are expected to grow faster than city hospitals—at a 16 percent compound annual growth rate from 2011 through 2020 versus a 13 percent rate for city hospitals over the same time period. But competing in this category comes with real challenges: lower profitability caused by dispersed distribution across locations and lower sales per hospital.

The broader basic health-care system is made up of community health-care centers in cities and township health-care centers in rural areas. This primary-care system will be the key area of competition for EDL drugs.

A Need to Understand the Factors That Drive Success

Adapting to new market forces requires a keen understanding of both the competitive dynamics in key drug segments and the challenge facing customers. Four sectors are of particular importance for pharmaceutical companies in the Chinese market—and what it takes to win in each sector is changing.

Patented Drugs in City Hospitals. This sector, long dominated by MNCs, has experienced relatively slow growth over the past few decades because of the long wait times to gain approval and reimbursement in China and because of MNCs’ focus on off-patent drugs. Increasingly, local companies will push to



develop competitive patented products. We expect that this sector will grow faster than before but that MNCs will continue to dominate.

Off-Patent Drugs in City Hospitals. Both MNCs and local companies compete in this sector, but MNCs in particular will feel the impact of changes. That's because MNCs built large sales forces for single-line detailing, a high-cost sales operation that was focused on city hospitals and was supported by the high premiums garnered by off-patent originator drugs. Going forward, those premiums will erode, making it harder to support the expensive (and increasingly less effective) sales practices, and off-patent originator drugs will face increasing competition from cost-effective branded generics marketed by local companies.

Off-Patent Drugs in County Hospitals. The county hospital market remains much smaller than the city hospital market and has been dominated by local pharmaceutical companies. MNCs have expanded to some large county hospitals in wealthy counties with select off-patent originator drugs. Going forward, however, the fast-growing county-hospital sector will become an important market for both MNCs and local companies. But the sector has its share of challenges: county hospitals are at the center of government reform, which includes a shift to eliminate markups on drugs, and local companies will fight aggressively for share with lower-priced drugs.

EDL Drugs in All Health-Care Institutions. Although MNCs have generally not participated in the EDL market in the past, the EDL sector will become harder to ignore. That's because it will grow much larger and use of EDL drugs will be enforced more aggressively in both city and county hospitals. But there will be significant price cuts for EDL drugs. As a result, this will remain the least profitable of the four sectors.²⁰

VI. Shanghai Medical Device Industry

Beijing and Shanghai are the two most interesting cities for the medical technology industries in terms of R&D. Although there is a small difference between the two cities (less than 5%), the differences between the regions are much more pronounced. For instance, the cities of Suzhou and Hangzhou together account for more than twice the number of patent applications of Tianjin. This is mainly due to the clustering effect of Shanghai and its high concentration of life science-related industries. Nevertheless, Tianjin has been developing rapidly in recent years in many fields, and medical technology has clearly become one of its pillar industries. Interestingly, in the southern China region, including Guangzhou and Shenzhen, the development of the medical technology industry is catching up very fast. Newly established companies and knowledge institutions such as Mindray, Edan Instruments, and the Shenzhen Institutes of Advanced Technologies (SIAT) are contributing heavily to the total number of patent applications. Furthermore cities in western China, such as Xi'an and Chengdu, are getting more and more attention as a result of the central government's 'Go-West' campaign.



As already mentioned, Shanghai region including Zhejiang and Jiangsu provinces is undoubtedly the hotspot for the medical technology industry. Top filing institutions from this region like Shanghai Jiaotong University, Zhejiang University, Southeast University, and Shanghai University of Technology are taking care of more than 50% of the total number of patent applications by the top-10 institutions. Furthermore, institutions from Beijing, Tianjin, and Shenzhen are also on this top-10 list. The third and fourth military medical universities from Chongqing and Xi'An respectively, are also consistently on the list.²¹

It is well-known fact that Shanghai possesses a solid industrial foundation. Whether it is in terms of product or technology, Shanghai's medical devices industry has always been seen as a "lynchpin" of China's medical devices industry. The Yangtze Delta Region with Shanghai as its center is one of three major medical devices industry clusters in China.

President Zhao explained that the Yangtze Delta region's medical devices industry cluster is growing rapidly, particularly for its small and medium enterprises. They possess strong industry characteristics. The medical devices industry in Yangtze Delta region possesses over half of the national market for disposal medical equipment and medical consummables. Of these, the more prominent ones are ophthalmic equipment industry in Suzhou, medical ultrasound devices industry in Wuxi, microwave and radiation tumor hyperthermia equipment industry in Nanjing and MRI industry in Ningbo. Coupled with the overall strength of Shanghai's medical devices industry, the performance of Yangtze Delta region industry cluster is indeed an exceptional one.²²

VII. China Market Overview

In November 2013, following the Third Plenum of the 18th Chinese Communist Party Congress, President Xi Jinping rolled out an ambitious agenda to re-shape the Chinese economy and fully embrace the market as the “decisive force” in shaping the country’s economic future. In order to continue China’s labor force evolution and to supplement the strong manufacturing exports that have fueled its unprecedented growth, Xi directed his administration to implement policy changes that increase domestic consumption, stimulate domestic innovation, and develop a world-class services sector – all the while expanding China’s middle class and moving millions of rural Chinese citizens to urban centers.

Market Challenges

The depth and complexity of China's proposed macroeconomic reforms bring with them significant challenges and pitfalls that will require skillful policy making and implementation. Problem areas to look out for include rising local debt, potential property bubbles, outflows of capital, shadow banking, excess capacity in industry sectors, and endemic corruption across industry sectors. China continues to make steady progress on the world stage as an emerging market in which to do business. The World Bank recently ranked China 96th (out of 189) in its Ease of Doing Business Report. However, China's explosive economic growth of the last several decades is beginning to slow. In 2013, real GDP grew 7.7 percent (down from 10.4 percent in as recently as 2010). While the government has set a 7.5 percent growth target, some economists predict that China's GDP growth will slow to 7.3 or 7.4 percent in 2014, which would represent China's slowest economic expansion since 1990. U.S. companies doing business in China remain concerned about rising costs for labor, enforcing intellectual property rights, competition with Chinese state-owned or state-supported companies, lack of transparency, burdensome bureaucracy, and protectionism in the business licensing and approval process.

Country Profile

- **Full name:** People's Republic of China
- **Population:** 1,355,692,576 (July 2014 est.)
- **Median Age:** 36.7 years (2014 est.)
- **Largest District:** Beijing
- **Area:** 9,596,960 sq km
- **GDP:** \$17.63 trillion (2014 est.)
- **GDP per capita:** USD \$12,900 (2014 est.)
- **Unemployment rate:** 4.1% (2014 est.)
- **Monetary unit:** 1 Renminbi yuan (RMB) (Y) = 10 jiao = 100 fen
- **Main exports:** Manufactured goods, including textiles, garments, electronics, arms
- **Investment in fixed capital:** 46%
- **Inflation rate:** 2.1% (2014 est.)

Source: CIA World Factbook

Market Opportunities

Despite these and other longstanding concerns, China remains an extremely attractive market for many U.S. companies. In fact, ninety percent of U.S.-China Business Council member companies responding to a USCBC survey report that their China operations are profitable, the highest percentage reported since 2006. Foreign direct investment into China saw modest growth in 2013, rising 5.3% year-on-year compared with a 3.7% drop in 2012. Furthermore, many of the economic reforms called for as part of the Third Plenum, particularly those related to foreign investment, are starting to take shape.

Some highlights so far include:

- Revising the three basic laws that govern foreign investment in China.
- Slashing the number of business or administrative approvals needed while delegating much of the approval responsibility to provincial or local government.



Global Resources. Local Expertise.

- Relaxing “paid in” and minimum registered capital requirements for foreign-invested enterprises, and replacing the annual government inspection procedure with an online filing system.
- Undertaking efforts to improve the legal and enforcement regime for intellectual property (IP) rights, and amending the trademark law to provide stronger protection and enforcement tools for all trademark owners.
- Liberalizing financial controls, including interest rates and limits on foreign exchange.

In a move that garnered significant attention, China established the Shanghai Pilot Free Trade Zone (SFTZ) in September 2013. Covering approximately 29 square kilometers in Shanghai’s Pudong district, the SFTZ was envisioned as a venue for China’s leaders to experiment with market-based reforms, such as relaxed controls on foreign investment, increased market access in industry sections not on a “negative list,” streamlined administrative procedures, and financial and foreign exchange reforms, but regulatory details are still slowly trickling out.²³

¹ [Emergo Executive Guide to Doing Business in Japan](#)

² [Healthcare Technologies Resource Guide: 2015 Edition](#)

³ [Doing Business in Japan: 2014 Country Commercial Guide for U.S. Companies](#)

⁴ [Healthcare Technologies Resource Guide: 2015 Edition](#)

⁵ <https://www2.deloitte.com/content/dam/Deloitte/global/Documents/Life-Sciences-Health-Care/gx-lshc-2015-life-sciences-report-japan.pdf>

⁶ <http://www.pharmaceutical-technology.com/features/featurejapans-pharma-industry-opening-up-to-the-world-4517216/>

⁷ [Doing Business in Japan: 2014 Country Commercial Guide for U.S. Companies](#)

⁸ [Healthcare Technologies Resource Guide: 2015 Edition](#)

⁹ [Doing Business in China: 2014 Country Commercial Guide for U.S. Companies](#)

¹⁰ [Healthcare Technologies Resource Guide: 2015 Edition](#)

¹¹ [Forbes, Health Care: A Trillion Dollar Industry in the Making](#)

¹² [MDDI: The Medical Device Market in China](#)

¹³ [PWC Asia-Pacific Health Industries Newsletter December 2014](#)

¹⁴ [USITC: Executive Briefings on Trade](#)

¹⁵ [PWC Asia-Pacific Health Industries Newsletter December 2014](#)

¹⁶ <http://www.thechinaperspective.com/topics/industry/china-pharmaceutical-industry/>

¹⁷ <http://www.ft.com/cms/s/0/ea2ed3e4-2c26-11e4-a0b6-00144feabdc0.html#axzz3dXCeEDFx>

¹⁸ http://www.pwccn.com/webmedia/doc/635691012746289994_pharma_cn_market_jun2015.pdf

¹⁹ <http://blogs.ft.com/ftdata/2013/09/24/chinaceutical/>

²⁰

http://www.bcg.com.cn/en/files/publications/reports_pdf/BCG_New_Rules_for_Winning_in_Chinaxs_Pharmaceutical_Market_Jan_2014.pdf

²¹ [Netherland Office for Science and Technology in China](#)

²² [MEDIT Expo: Characteristics of Medical Devices Industry in China's Pearl Delta and Yangtze Delta Regions](#)

²³ [Doing Business in China: 2014 Country Commercial Guide for U.S. Companies](#)